

ATTN: BOX -M. FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent of:

Kensil et al.

Patent No. 5,057,540

Issued: October 15, 1991

For: Saponin Adjuvant

Atty Docket: 0614.0350002/SLF

Statement Under 37 C.F.R. § 1.28(c)(2)

Assistant Commissioner for Patents Washington, DC 20231

Sir:

The undersigned, Lawrence B. Bugaisky, hereby declares and states that:

1. I am a Patent Agent at Sterne, Kessler, Goldstein, & Fox P.L.L.C. (SKGF) assigned responsibility for prosecuting the continuation application (U.S. Patent Application No.07/906,880, filed July 2, 1992 - herein the '880 application) of the above-captioned issued patent. When it was time to pay the issue fee for the '880 application, I became aware that the Small Entity status of that application was apparently established in error. Upon payment of the issue fee, I corrected the status of the application and paid the deficiency which was due. Since payment of the issue fee in the '880 application, however, I have also become aware that Small Entity status was incorrectly claimed for the above-captioned issued patent when paying the most recent maintenance fee on February 21, 1995. The change in status of the above-referenced patent results from the same information which changed the Small Entity status of the '880 application. I became aware of the error in claiming Small Entity status of the above-captioned patent for payment of the maintenance fee as follows.

- 2. The above-captioned issued patent was originally filed as U.S. Patent Application 7/200,754 (herein the '754 application) on May 31, 1988 as a Large Entity. Our records show that the application was filed under 37 C.F.R. § 1.53 without the declaration and filing fee. In response to the Notice of File Missing Parts dated July 6, 1988, applicants paid the filing fees as a large entity.
- 3. On August 27, 1990 a Rule 1.62 continuation (FWC) was filed from the '754 application. On October 5, 1990, a "Verified Statement (Declaration) Claiming Small Entity Status under 37 C.F.R. 1.9(f) and 1.27(c) Small Business Concern" was believed to have been correctly filed, as well as a request for a refund for previous payment of fees as a large entity. This request for a refund was repeated on December 13, 1994 because it came to the attention of SKGF that they had never received an indication that a credit was made to Deposit Account No. 19-0036.
- 4. On information and belief, on February 21, 1995, SKGF incorrectly paid the 3.5 year maintenance fee as a Small Entity. The payment of \$480.00 on February 21, 1995 as a Small Entity was incorrect because at the time of paying the maintenance fee, certain rights in the invention were already licensed to a large entity. Thus, Cambridge Biotech Corporation did not qualify as a small entity at the time of payment of the maintenance fee. To the best of my belief and knowledge there are no additional fees which were incorrectly paid as though the application was entitled to small entity status.

- 5. The error in Small Entity status for the above-captioned patent as applied to the payment of maintenance fees arises from the same set of facts as found for the '880 application. The error in the establishment of Small Entity status for the '880 application was discovered when preparing to pay the issue fee on the '880 application on February 23, 1996. In reply to a facsimile correspondence sent to Dr. Gerald Beltz of Cambridge Biotech Corporation on February 22, 1996 for final verification of small entity status, the undersigned was informed in a telephone conversation of the possibility that aspects of the technology related to the application had been previously licensed to a Large Entity, though the exact date was uncertain. On February 26, 1996, in a telephone conference with Karen Meenan of Cambridge Biotech Corporation and Jorge Goldstein of Sterne, Kessler, Goldstein & Fox, it was determined that certain rights concerning the '880 application as well as its grandparent application (the above captioned patent) had, in fact, been previously licensed to a large entity prior to payment of the maintenance fee.
- 6. On information and belief, the error in paying the 3.5 year maintenance fee on February 21, 1995 for the above-captioned patent occurred in good faith. The error in claiming Small Entity status appears to have occurred because such status was claimed based on the original establishment as a small entity which was correct. Even as recently as February of 1996 there appeared to be some confusion on the part of Cambridge Biotech Corporation concerning the fact that small entity status needed to be considered concerning specific applications, as opposed to the company as a whole. This confusion was clear in a correspondence from Dr. Charlotte Kensil related to the '880 application and dated as recently

as January 12, 1996, where it was stated that "Cambridge Biotech Corporation still has small entity status."

- 7. I became aware of the incorrect payment of the maintenance fee between February 26, 1996 and March 22, 1996 when reviewing the file of the above-captioned issued patent. At that time my secretary prepared an initial draft of the documents required for correcting the entity status. At some point thereafter, I realized that I would require authorization from Cambridge Biotech Corporation prior to filing the change in entity status.
- 8. On May 13, 1996 I requested authorization from Cambridge Biotech Corporation to file the appropriate documents and received their approval on May 15, 1996.
- 7. Thus, check no. 17068 in the amount of \$510.00 is provided herewith to cover the deficiency. To the best of my knowledge and belief, there are no additional fees which were incorrectly paid as though the application were entitled to small entity status. If such fees have, in fact, been overlooked, please charge these additional fees to our Deposit Account No. 19-0036. Two copies of this document are enclosed.
- 10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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